

## **REMARKS**

### **I. Status of the Claims**

Claims 1-3, 5-7, 9-11, 13, 16-18, 20, 23, 25-46, 50-63, 66-72, 83-126, 143, 152-164 and 167-186 are pending. Of those, claims 1, 5, 16-18, 20, 23, 25-29, 33-46, 50-63, 66-72, 83-126, 143, 152-164, 167, 185 and 186 are withdrawn and claims 2, 3, 6, 7, 10 and 174 are amended herewith. The claim amendments are made without prejudice or disclaimer and introduce no new matter. Claims 2, 3, 6, 7, 9-11, 13, 30-32, and 168-184 are presented for reconsideration.

In the discussion of the last amendment, the Office Action notes that the claims recited "said modulation being mediated by proteins extracted from tissue affected by the immune-related disorder, or at least one liver-associated cell of tolerized or non-tolerized subjects suffering from said immune-related or immune-mediated disorder or of said subject," and asserts that this language is inconsistent with claim 170, which recites that the NKT cells are cultured in the presence of both the proteins and the liver-associated cells. Applicants disagree with this assertion, noting that claim 2 recites "the method comprising," indicating that the method comprises the culture of NKT cells with the proteins or the cell, along with any other treatment. That other treatment could include NKT cell culture in the presence of the other of the proteins or cell. To clarify that the Applicants do not wish to preclude the culture of NKT cells in both proteins and cells, claims 2 and 3 were amended to recite "...said modulation being mediated by (a) proteins extracted from tissue affected by the immune-related disorder, or (b) at least one liver-associated cell of a tolerized or non-tolerized subject[[s]] suffering from said immune-related or immune-mediated disorder or of said mammalian subject, or (c) a combination thereof."

### **II. Restriction/Election**

The Office Action imposes a restriction requirement due to its assertion that "[t]he claims as amended appear to no longer encompass in their breadth the prior elected

species of 'culture conditions for the ex vivo education of NKT,' evidently because claim 7 was amended to delete the elected species "antigens or epitopes." In this regard, Applicants note that claim 9 makes clear that the proteins recited in the claims includes antigens. Therefore, Applicants assert that the previously elected species "antigens or epitopes" is in fact still encompassed by the claims as amended.

The Office Action imposes a restriction requiring selection of one of the following two species:

- I. Species 1, "proteins extracted from tissue affected by the immune-related disorder" and
- II. Species 2, "at least one liver-associated cell of tolerized or non-tolerized subjects suffering from said immune-related or immune-mediated disorder or of said subject".

In response, Applicants elect **Species 1**, directed to proteins extracted from tissue affected by the immune-related disorder. Claims not previously withdrawn that read on this species are 2, 3, 6, 7, 9-11, 13, 30-32, 168, 170-173, and 177-184.

The Office Action additionally imposes a restriction requiring selection of one of the antigens recited in claim 9 (as required with the election of Species 1). In response, Applicants elect **allogeneic antigens**. Claims of elected Species 1 reading on allogeneic antigens are 2, 3, 6, 7, 9-11, 13, 30-32, 168, 170-173, and 177-184.

The Office Action further imposes a restriction requiring selection of NKT cell culture conditions in the presence of "at least one cytokine" or "the adhesion molecule selection" or "at least one cytokine and the adhesion molecule selection" or "NOT cultured in the presence of at least one cytokine" or "the adhesion molecule selection". In response, Applicants elect **NOT cultured in the presence of at least one cytokine**. Claims of elected Species 1 reading on this elected species are 2, 3, 6, 7, 9, 13, 30-32, 168, 170-173, and 182-184.

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All elections are made without traverse.

### III. Conclusion

Applicants request substantive examination of the claims as amended, with consideration of the above elections.

While no fees are believed due with this response, Applicants authorize the United States Patent and Trademark Office to charge any unanticipated fees required to maintain pendency of this application to Deposit Account No. 05-1135.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that he be contacted at the number provided below.

Respectfully submitted,

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